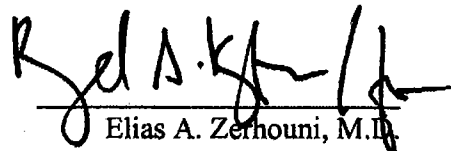


**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Report on the NIH Public Access Policy**

  
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## **Introduction**

In its report on the Fiscal Year 2006 appropriations for the Departments of Labor, Health and Human Services, and Education, the House Committee on Appropriations stated:

“The Committee is pleased that NIH is moving forward to implement its public access policy and is hopeful that the policy will be a first step toward providing free and timely access to the published results of all NIH-funded biomedical research. The Committee endorses NIH's expressed goals for the policy, namely to create an archive of NIH-funded research, to provide an opportunity to better manage the NIH research portfolio, and to provide enhanced public access to NIH research results. The Committee is concerned, however, that the final policy may not achieve these goals. For this reason, the Committee directs the Office of the Director to submit to the Committee by March 1, 2006 a comprehensive report on the progress achieved during the first eight months following the implementation of the new policy. Specifically, the Committee requests that the report provide: 1) the total number of applicable peer-reviewed articles deposited in PubMed Central since the May 2, 2005 implementation date; 2) the embargo period requested by the author for each deposited work; and 3) NIH's best estimate of the total number of applicable peer-reviewed articles available for deposit during this time frame, together with an explanation of the mechanisms relied upon to determine this estimate. Additionally, the Committee is concerned that grant recipients may not fully understand the NIH policy and the steps required to post an article in PubMed Central. The Committee, therefore, directs NIH to develop an aggressive education and outreach initiative aimed at informing grant recipients about the policy in an effort to maximize full and prompt participation.” (House Report No. 109-143, page 104)

In its report on the Fiscal Year 2006 appropriations for the Departments of Labor, Health and Human Services, and Education, the Senate Committee on Appropriations stated:

“The Committee has noted that the National Institutes of Health has begun to implement its public access policy which is geared to ensuring that NIH-funded research results are made available as soon as possible to the public, health care providers, educators, and scientists through the National Library of Medicine's PubMed Central [PMC] database. The Committee agrees with the need for, and a goal of, issuing a balanced policy to help promote increased public access to NIH-funded research while maintaining the integrity of the peer review system which is essential to ensure the quality and accuracy of medical research in the United States. The Committee urges NIH to work with all stakeholders as it moves forward in implementing this policy. To assist the Congress in assessing the degree of success of this new policy, the Committee requests a progress report by no later than February 1, 2006. Specifically, the Committee requests that the report contain the following information: (1) the total number of peer-reviewed articles deposited in PubMed Central since the May 2, 2005 implementation date and the distribution of chosen delay periods; (2) an assessment of the extent to

which the implemented policy has led to improved public access; (3) an assessment of the impact of the policy on the peer review system; and (4) the cost of operating the database.”

(Senate Report No. 109-103, page 159)

The following report has been prepared by the National Institutes of Health (NIH) of the Department of Health and Human Services in response to this request.

### **Background**

On February 3, 2005, the National Institutes of Health (NIH) announced a Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research, which has three important goals:

- To create a central archive of NIH-funded research publications;
- To advance science and enable NIH to better manage its research portfolio;
- To provide electronic access to the public to NIH-funded research publications.

The Policy requests NIH-funded investigators to submit their final, peer-reviewed manuscripts to the NIH National Library of Medicine's (NLM) existing PubMed Central (PMC) database upon acceptance for publication in a journal. Although the NIH strongly encourages that a manuscript be made available to other researchers and the general public immediately after it has been published in a journal, the Policy allows an author to delay the manuscript's release for up to 12 months.

Participation in the Public Access Policy is voluntary. This approach was developed to balance the legitimate concerns of publishers with the NIH goal of creating a permanently accessible central archive of peer reviewed research publications resulting from NIH-funded research.

NIH implemented the Policy on May 2, 2005. On that date, NLM released a web-based NIH Manuscript Submission (NIHMS) system to accept author submitted documents. The rate of submission to the NIHMS system in the first 8 months has been less than 4 percent of the total number of articles estimated to be eligible to have been added to PMC as a direct result of instituting the Policy.

### **Accomplishments**

#### *Articles Deposited and Delay Periods*

In the statements below, applicable articles are defined as those published, or slated for publication, after May 1, 2005.

- Number of applicable peer-reviewed articles deposited attributable to routine operations of the Policy between May 2 and December 31, 2005: 1,636.<sup>1</sup>
- Embargo period requested by authors: Of the 1,636 articles, 60 percent were specified for release upon the final date of publication; 23 percent were to be released 10 to 12 months after publication, and the remaining 17 percent fell in between. (See attachment 1 for additional details.)
- Estimate of the total number of applicable peer-reviewed articles available for deposit during this time frame: approximately 43,000. (This number excludes articles published in journals whose publishers already deposit the complete journal contents in PMC, as regular participants in NLM's digital archiving program. See Regular PMC Journal Deposits below for more detail.)

The estimate of the total number of articles available for deposit is based on an analysis of journal articles published in 2004, the latest year for which a complete publication record is available in PubMed. The estimate was derived by searching PubMed to obtain a count of articles published in 2004 that acknowledged NIH grant support or had authors with NIH intramural affiliations. That count was then reduced by the number of such articles that were published in journals routinely deposited in PMC as a result of pre-existing arrangements with their publishers. This yielded a total of approximately 65,000 articles that would qualify for deposit in PMC annually as a result of the Public Access Policy. Because the publication dates of the articles are distributed fairly evenly over the entire year, it is reasonable to estimate that the number of applicable or qualifying articles for the first eight months of the policy is two thirds of 65,000 or approximately 43,000 articles. This baseline does not include the small increase estimated to have occurred between 2004 and 2005 in the total number of articles published.

#### Regular PMC Journal Deposits

In 2004, approximately 5,400 articles that meet the criteria of the Public Access Policy were published in journals that are regular PMC participants. There was a slight increase in the number of such articles from 2004 to 2005, which is consistent with the corresponding increase in the overall number of articles resulting from NIH-funded research. We have not included articles from regular PMC participants in our estimate of the Policy's impact because their deposit is the result of a pre-existing program. If they were included in the equation, the base of applicable articles available for deposit would grow to 70,400 for a year, or 47,000 articles for the first eight months of the policy. These articles in regular PMC journals would account for just under 8 percent of the total number of articles in the expanded baseline for the eight-month period.

#### *Assessment of the Extent to which the Policy has Improved Public Access*

Adding articles to PMC improves the public's access to them, either immediately or when their specified embargo periods elapse. From May through December 2005, the

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<sup>1</sup> 1,311 articles submitted to the NIHMS in this period were published before May 2005, some as early as 2003. These pre-May 2005 articles are not included in the 1,636 count because their retrospective character makes them a one-time event and not representative of ongoing activity.

Policy led to the addition of 1,636 new articles to the PMC archive, thus improving access to 3.8% of the estimated new 43,000 articles that could have been deposited as a result of the policy.

There has been steady growth in the use of PMC as the number of articles it contains increases. During the reporting period, the contents of the PMC database grew from 371,000 to 515,000 articles overall, and 6.8 million unique users viewed some 32 million copies of these articles.

#### *Impact of the Policy on the Peer Review System*

The NIH has no evidence to indicate that the Policy has had any impact on peer review. The Policy endorses existing peer review mechanisms by making it clear that manuscripts should be deposited only AFTER they have gone through peer review and been accepted for publication in a journal.

#### *Cost of Operating the Database*

NLM developed the NIH Manuscript Submission System (NIHMS) to manage the intake of author manuscripts to PMC. The submission process is designed to be simple and quick, accepting manuscripts in whatever format an author submits them to the applicable journal. The manuscript submission system is built on an existing robust information technology infrastructure at NLM. The incremental cost for basic staffing, hardware, software acquisition and maintenance, and conversion of documents to a standard PMC archiving format was \$1 million in FY 2005. Based on current and estimated expenditures, the incremental annual cost would rise to \$2 million if 50% of eligible manuscripts were submitted and to \$3.5 million if there was full compliance (i.e., submission of 65,000 articles per year).

#### **Planned Activities**

##### *NIH has implemented and continues an Aggressive Education and Outreach Initiative Aimed at Informing Grant Recipients about the Policy in an Effort to Maximize Full and Prompt Participation*

The NIH is using a variety of media and methods to publicize the Public Access Policy. This effort has been focused around three major goals: (1) Educating NIH Staff to help Principal Investigators (PIs) follow the Policy; (2) conducting outreach to PIs and Grantee institutions; and (3) outreach efforts to publishers. These efforts are summarized in Attachment 2.

The NIH has made a concerted effort to educate NIH staff, both to encourage their own participation and support the efforts of extramural grantees. These efforts have included: in person updates at NIH senior leadership meetings; an NIH Staff town hall meeting; monthly updates in the NIH extramural staff policy update, the *OER Insider*; and distribution of several letters and emails to NIH staff directly from the NIH Director and other senior officials.

The NIH has also taken several steps to communicate the Policy to PIs, Grantees and other stakeholders. We have issued press releases and have sent letters and emails directly to all Grantees. Since October, NIH includes information about the Policy in its Notice of Grant Awards, which is sent to all Grantees at the time of funding. Finally, NIH senior officials have made over 30 presentations at stakeholder and professional meetings to explain the Policy. These included meetings of the following organizations:

- American Association for the Advancement of Science
- Association of Academic Health Sciences Libraries
- Association of American Medical Colleges
- Association of American Universities
- Society of Research Administrators
- American Institute of Biological Sciences
- Medical Library Association and several of its regional chapters

The NIH is also actively working to inform journals about the Policy. NIH has made several formal presentations to publisher groups, including the Association of American Publishers, the American Medical Publishers Association, and the Council of Science Editors. NIH also corresponds regularly with publishers concerning the submission process or the Policy in general. Our goal is to assure an open line of communication with publishers to improve the Policy, where possible, and build a robust archive of NIH-funded research manuscripts.

The NIH is reviewing the impact of this outreach effort. Based on this review and information from an informal survey of faculty and research administrators at 19 universities by the Association of Academic Health Sciences Libraries, the majority of NIH-funded scientists are aware of the Policy. This finding has been corroborated by a focus group of NIH staff researchers, NIH extramural investigators and NIH program staff held in December 2005, and by members of NIH advisory committees. Lack of awareness therefore does not appear to be the primary reason for the low submission rate.

### **Issues**

#### ***NIH is Working With All Stakeholders as NIH Moves Forward in Implementing this Policy***

An NIH Public Access Working Group of the NLM Board of Regents was established in May 2005. Its 17 members represent the range of stakeholders in the Policy: researchers, journal publishers, scientific societies, librarians, disease advocacy organizations and the general public. Its charge is to (1) review the statistical evidence on the impact of the Policy, (2) provide suggestions for improving implementation, (3) assess how well the Policy is achieving the NIH goals, and (4) suggest changes to the Policy that might further these goals. A list of working group members, the text of its charge, and the minutes of its meeting are available from <http://www.nlm.nih.gov/od/bor/bor.html>.

Given evidence that scientists are aware of the Policy, the Working Group's discussion at its most recent meeting on November 15, 2005 revolved around three questions:

- Should investigators' participation in the Policy be mandatory or voluntary?
- Which version of an article should be deposited in PMC: the author's final peer-reviewed manuscript, or the final, edited article as it is published in the journal?
- What should be the length of the embargo period before public access to an article is permitted through PMC?

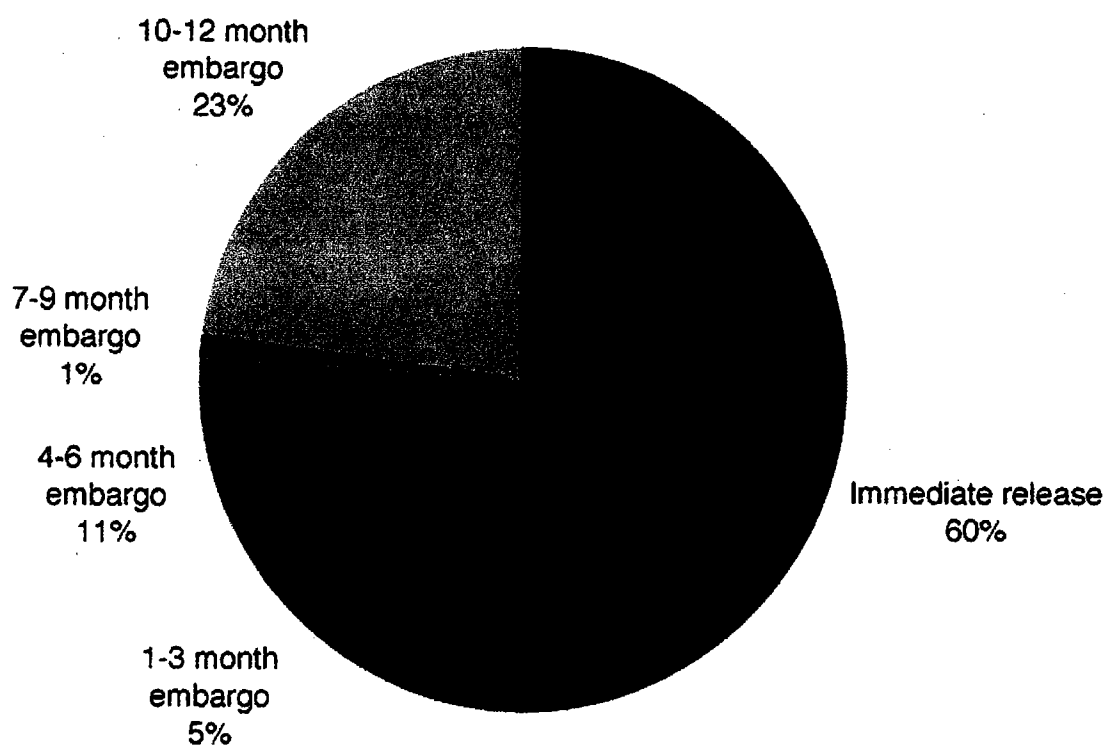
Excluding the two NLM Regents who chair and co-chair the Group, eleven Working Group members were in attendance and provided their opinions during the discussion. Nine expressed the belief that the NIH Policy could not achieve its goals unless deposit of manuscripts was mandatory. Ten felt that it would be highly desirable to have investigators deposit the final, edited article as it is published in the journal. Eight members felt public access to an article should occur within 6 months, but there was general consensus that flexibility in the policy was necessary to extend this embargo period to 12 months in special cases (e.g., for journals that are published quarterly or less frequently). The NLM Board of Regents will consider the opinions of the Working Group at its next meeting.

### **Conclusions**

NIH implemented the Policy on May 2, 2005. The rate of submission to the NIHMS system in the first 8 months has been less than 4 percent of the total number of articles estimated to be eligible to have been added to PMC as a direct result of instituting the Policy. Lack of awareness does not appear to be the primary reason for the low submission rate. NIH continues to work with researchers, journal publishers, scientific societies, librarians, disease advocacy organizations and the general public to improve public access.



**Attachment 1**  
**Embargo Period Requested by Authors**  
**for All Articles Published after**  
**May 1, 2005**



## Attachment 2: Overview of Public Access Policy Outreach Efforts

